EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2064405-1

Manufacturer: **Reach Surgical, Inc.**
120 Xinxing Road, West Zone, TEDA,
300462 Tianjin
P.R. China

EUDAMED Single Registration No.: CN-MF-000011148

Products:

Products of class IIa:
H020301 - LINEAR STAPLERS FOR VIDEOSURGERY

Products of class IIb:
H020301 - STAPLERS FOR VIDEOSURGERY
LINEAR STAPLERS FOR VIDEOSURGERY
Z120108 - GENERAL AND MULTIDISCIPLINARY SURGERY INSTRUMENTS
INSTRUMENTS FOR ULTRASONIC SURGERY
K020201 - DEVICES FOR SURGERY WITH ULTRASONIC GENERATOR, SINGLE-USE
ULTRASONIC SURGERY INSTRUMENTS, SINGLE-USE

Authorised representative(s): **Medical Device Safety Service GmbH (MDSS)**
Schiffgraben 41, 30175 Hannover, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-11-22

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190141164-120

Effective date: 2023-11-22

Expiry date: 2028-11-21

Issue date: 2023-11-22

TÜV Rheinland LGA Products GmbH Zertifizierstelle

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Podpisane elektronicznie przez Karolina Anna Szatkowska-Zawisza (Certyfikat kwalifikowany) w dniu 2025-02-20.